

## ORDER AND DIRECTIVE CONCERNING ADVANCED PAIN MEDICINE INSTITUTE No. MDH 2020-06-27-01

I, Robert R. Neall, Secretary of Health, finding it necessary for the prevention and control of 2019 Novel Coronavirus ("SARS-CoV-2" or "2019-NCoV" or "COVID-19"), and for the protection of the health and safety of residents, staff, and other individuals in Maryland, hereby authorize and order the following actions for the prevention and control of this infectious and contagious disease under the Governor's Declaration of Catastrophic Health Emergency. It is hereby ORDERED that the following occur:

- 1. A COVID-19 test specimen collection site located at Bethel Korean Presbyterian Church, 3165 St. Johns Lane, Ellicott City, 21042, and operated by staff affiliated with **Advanced Pain Medicine Institute** (APMI), 7501 Greenway Center Drive, Suite 660, Greenbelt, MD 20770, on June 27, 2020 from 10 A.M. 4 P.M. shall not collect COVID-19 test specimens to be processed by APMI due to concerns about the use of potentially unvalidated PCR assays and the lack of a laboratory medical director. If specimens are collected at this site for COVID-19 testing, they shall only be processed by a CLIA-approved laboratory.
- 2. The Howard County Health Department shall take actions necessary for the preservation of public health and to prevent and control COVID-19 at the above COVID-19 test specimen collection site, including, but not limited to closing the testing site.
- 3. The Maryland Department of Health's (MDH) Office of Health Care Quality is to take actions necessary for the enforcement of federal and state laws and regulations by ensuring that APMI is a licensed CLIA-approved laboratory in good standing and with the appropriate authorizations to conduct COVID-19 test analysis on COVID-19 specimens.
- 4. APMI shall not collect or process COVID-19 specimens from any COVID-19 specimen collection site in Maryland, unless authorized by MDH's Office of Health Care Quality.
- 5. APMI shall not use State of Maryland logos or branding in any public messaging. Further, APMI shall not represent that it is authorized to conduct COVID-19 testing to the public until further notice.
- 6. APMI shall immediately notify all patients tested for COVID-19 that the results of the COVID-19 testing by PCR method conducted by APMI are invalid or erroneous. The notification must inform patients previously tested for COVID-19 that they should consider alternate testing or retesting, as appropriate.
- 7. APMI shall place a public notice on its website and any other websites affiliated with APMI to indicate that they are not certified to provide COVID-19 specimen collection or

conduct laboratory analysis of COVID-19 specimens. The public notice shall include information informing patients previously tested for COVID-19 to consider alternative testing or retesting as appropriate.

- 8. APMI shall, within 24 hours, provide the MDH, Epidemiology Unit, with a complete list of all individuals tested, including demographics, contact information, results of each test (positive, negative, or pending). The information shall be provided to David Blythe, State Epidemiologist, at <a href="mailto:david.blythe@maryland.gov">david.blythe@maryland.gov</a>.
- 9. APMI shall fully cooperate with all MDH instructions and any further instructions by local health departments in contacting the patients tested.
- 10. APMI shall take immediate steps to protect the personal information and protected health information of any patients tested, including but not limited to providing MDH with a detailed explanation of how protected health information is being protected, including copies of all relevant Business Associate Agreements.

THESE DIRECTIVES AND ORDERS ARE ISSUED UNDER MY HAND THIS 27TH DAY OF JUNE 2020 AND ARE EFFECTIVE IMMEDIATELY FOR 30 DAYS.

Robert R. Neall

Secretary